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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,922	10/21/2003	James G. Whayne	CNVG-005US3CON	6918

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EXAMINER

POUS, NATALIE R

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/690,922

Applicant(s)

WHAYNE, JAMES G.

Examiner

Natalie Pous

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/21/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The abstract of the disclosure is objected to because the word "being" is repeated in line 7. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. (US 6056762) in view of Yencho et al (US 6206913).

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Nash teaches a method and apparatus for forming an anastomosis between a host vessel and a bypass graft comprising the following:

- Providing an anastomotic fitting (500) comprising a base (202) having a proximal and distal end
- A leading segment (502) extending from the distal end of the base, the leading section having a cross section approximating the radius of curvature of the host vessel (fig. 19)
- A rear segment (504) extending from the distal end of the base and being deflectable (Column 14, proximate lines 32-39)
- Deflecting the rear segment; advancing the leading segment into the host vessel wall opening; and releasing the deflected rear segment whereby the rear segment is positioned within the host vessel (Column 14-15, proximate lines 46-68 and 1-13 respectively)
- Wherein the rear segment is deflected toward the base and leading segments (Column 14, proximate lines 49-50)
- Forming an angled connection of between about 30 degrees and 150 degrees between the graft vessel and the host vessel (fig. 19)
- A means for positioning the fitting within an opening in a wall of the host vessel, the positioning means comprising a means for deflecting the rear segment (Column 14, proximate lines 60-65)
- A support device (62); and means for securing the support device to the base of the fitting (48)

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Nash fails to teach:

- The leading segment comprising open spaces throughout the surface area
- Compressing the leading segment into a reduced cross-section prior to advancing the leading segment through the opening in the host vessel wall
- The compressing is facilitated by the open spaces within the leading segment
- Advancing the leading segment comprises using the leading segment to dilate the opening wherein the leading segment is smoothly transitioned into the opening

Yencho teaches a system for attaching a graft to a blood vessel wherein the leading segment (distal portion 14) comprises open spaces throughout the surface area (fig. 9) Compressing the leading segment into a reduced cross-section prior to advancing the leading segment through the opening in the host vessel wall (fig. 8), wherein the compressing is facilitated by the open spaces within the leading segment and wherein the leading segment is smoothly transitioned into the opening in order to insert the device in the smallest incision possible and reduce trauma to the target vessel (Column 4, proximate lines 15-23). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the leading portion of Nash with open spaces and compress the leading edge for insertion as taught by Yencho in order to insert the device in the smallest incision possible and reduce trauma to the target vessel. It is noted that inserting an expanding member into a vessel incision will inherently dilate the incision to some extent, as vessels are compliant and dilate or change shape even under a small amount force.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Nash and Yencho as applied to claim 20 above, and further as a matter of design choice. The combination of Nash and Yencho teaches all limitations of preceding dependent claim 20 as previously described, but fails to teach wherein the rear segment has a length less than the diameter of the host vessel. Nash has not disclosed a specific length for the rear segment but it would have been an obvious matter of design choice to disclose the length of the rear segment with a length less than the diameter of the vessel since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller* 105 USPQ 233.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13-26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6702828. Although the conflicting claims are not identical, they are not patentably distinct from each other because they relate to the same inventive concept. The instant application and the patent are both directed to anastomosis device having a base with a leading segment or leaf and a deflectable distal segment or leaf, and wherein the device has a cross-section with a radius of curvature of the radius of curvature of the host vessel.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
7/20/06



(JACKIE) TAN-UYEN HO
PRIMARY EXAMINER
7/24/06